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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,841	11/28/2000	Kenneth H. Grabstein	2811-H	6624

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IMMUNEX CORPORATION
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EXAMINER

MERTZ, PREMA MARIA

ART UNIT PAPER NUMBER

1646

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,841

Applicant(s)

GRABSTEIN ET AL.

Examiner

Prema M Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-30, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-30, 34-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/5/2004 has been entered.

Claims 21-30 and 34-35 and amended claim 20 (2/5/200) are pending in the instant application. Claims 1-19, 31-33 and 36-40 have been canceled.

Specification

2a. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

2b. Applicants are requested to update the status of the prior applications to which the instant application is claiming benefit. The status of nonprovisional parent 09/189,193 should be updated and the expression, "now U.S. Patent No. 6,184,359" should follow the filing date of the parent application.

2c. The disclosure is objected to because of the following informalities:

On page 10, lines 25-30, the old address of ATCC in Rockville, MD is disclosed. The new address is ATCC, 10801 University Boulevard, Manassas, VA 20110-2209.

Appropriate correction in the specification is required.

Claim rejections-35 USC § 112, first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 20 recites “at least 12 contiguous nucleotides” which language is new matter in the claim, since the instant specification fails to disclose such a limitation. The specification fails to provide proper support for this language in the claims for the following reason:

In the specification page 12, discloses:

Antisense or sense oligonucleotides comprise single-stranded nucleic acid sequences (either RNA or DNA) capable of binding to sense ETF mRNA or antisense ETF cDNA sequences. An antisense or sense oligonucleotide, according to the present invention comprises a fragment of the nucleotide sequences in Figures 1 or 2 or a DNA or RNA complement of the nucleotide sequences in Figures 1 and 2. Such a fragment comprises at least about “14 nucleotides” and is capable of binding to ETF DNA.

The specification does not disclose the specific limitations of “at least 12 contiguous nucleotides” or “18 to 20 nucleotides” or “20 to about 75 nucleotides” as recited in the claims 20-25. This rejection can only be obviated by reciting the specific nucleic acid length for which there is support in the instant specification.

Claim rejections-35 USC § 112, second paragraph

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4. Claims 20-30 and 34-35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 confusing "...in length from SEQ ID NO:1....". It is suggested that for clarity the claim be amended to recite the Markush format as follows "...in length selected from the group consisting of

- (a) a nucleic acid consisting of SEQ ID NO:1,
- (b) a nucleic acid consisting of SEQ ID NO:4,
- © a nucleic acid complementary to SEQ ID NO:1, and
- (d) a nucleic acid complementary to SEQ ID NO:4."

Similarly SEQ ID NO:28 should be amended to recite the appropriate Markush format.

Appropriate correction is requested.

With respect to claim 34 the recitation of "any combination thereof" is vague and indefinite because it is unclear why both the DNA and RNA (corresponding to the nucleic acid claimed) would be used together.

Claims 21-27, 29-30, 35 are rejected as vague and indefinite insofar as they depend on the above rejected claims for their limitations.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-22, 26-27, 34, 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al (1991).

The reference discloses the genomic and cDNA sequences for the mouse cellular retinal binding protein 1 (mCRBP1) cDNA (see abstract, lines 1-2) and Figure 1(A) on page 2224). Nucleotides 51-63 of the mouse CRBP1 cDNA are 100% identical to nucleotides 1-13 of SEQ ID NO:1 in the instant application. The reference also teaches that the first 80 nucleotides of the cDNA labeled with 32-P at the 5' end were used for screening a mouse genomic λ EMBL3 library (see page 2229, in Materials and Methods, second full paragraph, first 3 lines). Therefore, the cDNA of the reference meets the limitations of a nucleic acid of at least 12 contiguous nucleotides in length from SEQ ID NO:1 and anticipates instant claims 20-22, 26-27, 34, 35.

Conclusion

No claim is allowable.

Applicants are advised that with respect to claim 20, the limitation "from SEQ ID NO:1..." for example, has been interpreted by the Examiner as reading on closed language encompassing only SEQ ID NO:1 and no additional sequences.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 271-0871.

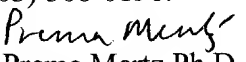
Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

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All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Prema Mertz Ph.D.
Primary Examiner
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March 10, 2004